



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,570	02/08/2002	Susanne Buser	R0134A-REG	2583

7590

03/05/2004

Rohan Peries  
Roche Bioscience  
Patent Law Dept. M/S A2-250  
3401 Hillview Avenue  
Palo Alto, CA 94304

EXAMINER
----------

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
----------	--------------

1614

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/071,570

Applicant(s)

BUSER ET AL.

Examiner

Brian S Kwon

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,7-19,21 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 20, 22-24 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Summary of Action***

- I. The objection to specification will not be maintained in light of the amendment.
- II. The claim objection will not be maintained in light of the amendment.
- III. The rejection the claim under 35 USC 112, second paragraph, will not be maintained in light of the amendment.
- IV. Claim 20 is objected.
- V. The rejection of the claim under 35 USC 102(b) will be maintained for the reason of the record.
- VI. The rejection of the claims under 35 USC 103(a) will be maintained for the reason of the record.
- VII. The rejection of the claims under the judicially created doctrine of double patenting will be maintained for the reason of the record since no terminal disclaimer has been submitted.
- VIII. It appears that the examiner inadvertently checked box the line 14 of Office Action Summary mailed 9/10/2003, acknowledging the domestic priority claim under 35 USC 119(e). Please disregard the examiner's acknowledgment. In this Office Action, acknowledgment is made of applicants' claiming for foreign priority (EP 01109853.0 filed 04/23/2001) under 35 USC 119(a)-(d) or (f).

***Status of Application***

1. By Amendment filed December 08, 2003, Claims 2, 3, 6 and 20 have amended. Claims 1-3, 6, 20 and 22-24 are currently pending for prosecution on the merits.

***Applicants Response to Restriction Requirement Acknowledged***

2. Applicants' confirmation of the provisional election with 2-(3,5-bis-trifluoromethyl-phenyl)-N-[6-(1,1-dioxo-1 $\lambda$ 6-thiomorpholin-4-yl)-4-o-tolyl-pyridin-3-yl]-N-methyl-isobutyramide as the elected species is acknowledged.

Applicants traverse that claims 7 and 9 also read upon the elected species as being directly depend on claim 6 and should be examined together with claims 3, 6, 20 and 22-24. This argument is not persuasive at all. Unlike applicants' argument, none of the claimed species recited in claims 7 and 9 read on the elected single species, 2-(3,5-bis-trifluoromethyl-phenyl)-N-[6-(1,1-dioxo-1 $\lambda$ 6-thiomorpholin-4-yl)-4-o-tolyl-pyridin-3-yl]-N-methyl-isobutyramide. Because claims 7 and 9 are being dependent claims of claim 6 which encompasses the elected species does not necessarily mean that the dependent claims (claims 7 and 9) encompass the elected species. The examiner determines that it is proper to withdraw claims 7 and 9 along with 4-5, 8, 10-19, 21 and 25 from further consideration, as being drawn to a non-elected invention.

***Priority***

3. Receipt is acknowledged of papers (EP 01109853.0 filed 04/23/2001) submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Claim Objections***

4. Newly amended claim 20 is objected to because of the following informalities: typographical error “2-(3,5-bis-trifluoromethyl-phenyl)-N-[6-(1,1-dioxo-1□<sub>6</sub>-thiomorpholin-4-yl)-4-o-tolyl-pyridin-3-yl]-N-methyl-isobutyramide” and “2-(3,5-bis-trifluoromethyl-phenyl)-N-[6-(1,1-dioxo-1□<sub>6</sub>-thiomorpholin-4-yl)-4-(4-fluoro-2-methyl-phenyl)-pyridin-3-yl]-N-methyl-isobutyramide”. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Fritz et al. (WO 99/07681).

This rejection is analogous to the original rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1614

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 2-3, 6, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bos et al. (GB 2347422) in view of Fritz et al. (WO 99/07681).

This rejection is analogous to the original rejection.

#### ***Response to Arguments***

7. Applicant's arguments filed December 08, 2003 have been fully considered but they are not persuasive.

Applicant's argument takes position that Fritz's teaching in using NK1 receptor antagonist in treatment of irritative symptoms of benign prostatic hypertrophy differs from the instantly claimed treatment of BPH since "the treatment of irritative symptoms does not automatically correspond to treatment of the underlying disease or condition that gives rise to such symptoms". This argument is not persuasive at all.

The scope of the instantly claimed “treating benign prostatic hyperplasia” encompasses the treatment of various symptoms of benign prostatic hyperplasia regardless of whether the underlying disease or condition is effectively treated or not. Unlike applicants’ allegation, the term “treatment or treating” in plan, ordinary sense means controlling, reducing, alleviating or treating symptoms of the disease or condition as well as the treatment of the disease or condition. Therefore, the reference anticipates the claimed invention.

Applicants’ argument takes position that the selection of treatment of BPH from approximately 100 different types of diseases listed in Fritz would not have been apparent to those skilled in the art. Applicants alleges that the skill artisan would not reasonably look to teachings of Fritz t in attempting to develop treatments of BPH by NK-1 receptor antagonist since the known uses of NK-1 receptor antagonists are typically identified with the treatment of pain by persons skilled in the art. The examiner disagrees.

Unlike applicant’s alleged “a very long list of indications that are purportedly treatable with NK-1 receptor antagonist which encompass approximately 100 diseases”, Fritz discloses irritative symptoms of benign prostatic hypertrophy as one of most preferred disease condition among other approximately 35 disease conditions that can treated by NK-1 receptor antagonist in addition to pain (page 43, line 23 thru page 44, line 3). Unlike applicants’ allegation, the skill artisan would be able to “at once envisage” the treatment of irritative symptoms of benign prostatic hypertrophy by NK-1 receptor antagonist. Therefore, the reference anticipates the claimed invention.

Applicants' argument takes position that there is no teaching or suggestion by Fritz et al. of the use of NK-1 receptor antagonists for reduction of prostate size as disclosed by applicants. This argument is irrelevant to the issue. As discussed above, the instant invention is directed to the treatment of benign prostatic hyperplasia by NK-1 receptor antagonist. There is no mention of "reduction of prostate size" in the claims. The discussion of "reduction of prostate size" in response to the administration of NK-1 receptor antagonist is totally irrelevant to the instantly claimed invention. Therefore, the examiner will not respond to this argument.

In response to the claim rejection under 35 USC 103(a), similarly to the argument presented in response to the examiner's claim rejection under 35 USC 102(b), applicants allege that "Fritz et al., does not disclose treatment of BPH per se as disclosed and claimed by Applicants...Skilled persons would not be motivated, from the teaching of Bos et al., or Fritz et al, to use the compounds of formula (I) for treatment of BPH". This argument is found unpersuasive similarly to the examiner's preceding comments. The examiner maintains that one having ordinary skill in the art would have expected as taught by Fritz that inappropriate stimulation of neurokinin 1 (NK-1) receptor is implicated in benign prostatic hypertrophy and NK-1 receptor antagonist is useful in relieving irritative symptoms of benign prostatic hypertrophy. Therefore, one having ordinary skill in the art would have been motivated to administer the claimed compounds having NK-1 receptor antagonist activity, with the reasonable expectation of success, to subjects suffering from irritative symptoms of benign prostatic hypertrophy such that said NK-1 receptor antagonists would effectively reduce the symptoms of benign prostatic hypertrophy.



### ***Conclusion***

8. Applicant's amendment necessitated a new ground of rejection in this Office Action.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. No Claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (571) 273-0584. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Application/Control Number: 10/071,570  
Art Unit: 1614

Page 9

Brian Kwon  
Patent Examiner  
AU 1614

**ZOHREH FAY**  
**PRIMARY EXAMINER**  
**GROUP 1600**

*Zohreh Fay*